Carolina for his treatment and was charged the AWP for Lupron® each time. As a retired member of the armed services, Mr. Nelson had CHAMPUS medical insurance coverage which paid for 75% of his Lupron® prescription purchases. The remaining 25% co-payment was paid in full directly by Mr. Nelson. Accordingly, Mr. Nelson suffered direct injury and damages as a result of Defendants' unlawful conduct set forth herein.

28. Plaintiff, Michael de Montbrun,, is an individual and resident of the State of North Carolina who resides in Wilmington, New Hanover County, North Carolina. Mr. de Montbrun was diagnosed with prostate cancer and has been prescribed and has taken Lupron® for the treatment of his condition. He has made several purchases of Lupron® in North Carolina for his treatment and was charged the AWP for Lupron®. Mr. de Montbrun has Medicare Part B which pays for 80% of his Lupron® prescription purchases. The remaining 20% co-payment has been paid in part directly by Mr. de Montbrun and in part by his private insurer. Accordingly, Mr. de Montbrun suffered direct injury and damages as a result of Defendants' unlawful conduct set forth herein.

29. Defendant Abbott Laboratories ("Abbott") is a highly diversified health care corporation whose principal business is the discovery, development, manufacture, and sale of a broad and diversified line of health care products and services. Abbott's business includes pharmaceuticals, nutritionals, hospital products, and diagnostics. Abbott's world headquarters is located in Abbott Park, Illinois. The company employs over 60,000 people and reported sales of $13.7 billion for the fiscal year ended December 31, 2000.

30. Defendant Takeda Chemical Industries LTD ("Takeda") is Japan's largest pharmaceutical company and is among the largest in the world. Headquartered in Osaka, Japan,

Takeda discovers, develops, manufactures and markets a broad range of pharmaceutical products. Takeda Pharmaceuticals America was created to take advantage of Takeda's growing, international pharmaceutical presence. Takeda Pharmaceuticals America's U.S. headquarters is in Lincolnshire, Illinois. Takeda's net sales for Financial Year 1999 were $8.7 billion.

31. Defendant TAP Pharmaceutical Products Inc. ("TAP") is a partnership between Takeda and Abbott. TAP's United States headquarters is located at 675 North Field Drive, Lake Forest, Illinois 60045. Under a partnership agreement between Abbott and Takeda, TAP (owned 50 percent by Abbott and 50 percent by Takeda), together with its subsidiary, TAP Pharmaceuticals, Inc., develops and markets pharmaceutical products for the United States and Canada. One of these products is leuprolide acetate (for depot suspension), a synthetic nonapeptide analog of naturally occurring gonedotropin-releasing hormone (Gn RH or LH-RH). The brand name for the drug is Lupron® or Lupron Depot® (a sustained release form of Lupron®) (collectively referred to herein as "Lupron®").

32. According to Abbott's recent Form 10-K filed February 15, 2001, Lupron® is sold directly to physicians, retailers, wholesalers, health care facilities, and government agencies. It is distributed from Abbott-owned distribution centers. TAP's primary marketing efforts are focused on securing the use of Lupron® by physicians. In 1998, the total revenues from Lupron® sales through Medicare was $584 million consisting of 80% paid by the federal government ($467 million) and 20% paid by Plaintiff Stetser and members of the plaintiff Class ($117 million). TAP's total sales revenue in 1998 was $2.06 billion.

33. Defendant Johnson & Johnson ("J&J") is a highly diversified health care corporation organized and existing under the laws of the State of New Jersey with a principal place of business

and corporate headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material hereto, J&J, by and through its wholly owned subsidiary companies Ethicon and Indigo, and their respective officers, directors, employees and agents, including Defendants Jett, Coleman and Hidalgo, was in the business of manufacturing, promoting, marketing, distributing and selling healthcare products and services to medical providers, among others.

34. Defendant Ethicon Endo-Surgery, Inc. ("Ethicon"), a wholly owned subsidiary of J&J, is a corporation organized and existing under the laws of the State of Ohio with a principal place of business and corporate headquarters at 4545 Creek Road, Cincinnati 45242. In 1996, Ethicon acquired Indigo Medical, Inc., a urology device company that manufactures and sells the Indigo LASEROPTIC Treatment System for BPH. At all times material hereto, it is believed and therefore averred that Ethicon, by and through its wholly owned subsidiary company Indigo Laser Corp., and its officers, directors, employees and agents, including Defendants Jett, Coleman and Hidalgo, was in the business of manufacturing, promoting, marketing, distributing and selling healthcare products and services to medical providers, among others.

35. Defendant Indigo Laser Corporation ("Indigo"), a wholly owned subsidiary of Ethicon and J&J, is a corporation organized and existing under the laws of the State of Ohio with a principal place of business and corporate headquarters in Cincinnati, Ohio. In 1996, Indigo's predecessor, Indigo Medical, Inc., was acquired by Ethicon. At all times material hereto, it is believed and therefore averred that Indigo, by and through its officers, directors, employees and agents, including Defendants Jett, Coleman and Hidalgo, was in the business of manufacturing, promoting, marketing, distributing and selling healthcare products and services to medical providers, among others.

36. Defendant David Jett is an individual and resident of the State of North Carolina who, at all times material hereto, was employed as a sales representative of Indigo in and around Mount Pleasant, North Carolina.

37. Defendant Christopher Coleman is an individual and resident of the State of North Carolina who, at all times material hereto, was employed as a sales representative of Indigo in and around Greensboro, North Carolina.

38. Defendant Scott Hidalgo is an individual and resident of the State of Florida who, at all times material hereto, was employed as a sales representative of Indigo in and around Orlando, Florida.

39. Defendant Eddy James Hack is an individual resident of the State of Florida who, at all times material hereto, was the owner and operator of Oncology Solutions a/k/a International Oncology Network, a nationwide, community-based oncologist network.

PLAINTIFFS' CLASS ALLEGATIONS

40. Plaintiffs seek to bring this case as a class action pursuant to Rule 23(a) of the North Carolina Rules of Civil Procedure, N.C.G.S. 1A-1, Rule 23(a) (1983), on behalf of themselves and all others similarly situated in North Carolina and throughout the United States as members of a proposed class, defined as follows (the "Class"):

> All persons and entities in North Carolina and throughout the United States who paid any portion of the cost of Lupron®, which cost was based upon, in whole or in part, the published AWP for Lupron®. Excluded from the Class are Defendants, any entity in which Defendants have a controlling interest, and their legal representatives, heirs, successors, and any governmental entities.

41. Alternatively, Plaintiffs seek to bring this case pursuant to Rule 23(a) on behalf of the following sub-class (the "Indirect Purchaser States Sub-Class"):

> All persons and entities in North Carolina and the states of Arizona, California, District of Columbia, Florida, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Dakota, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin who paid any portion of the cost of Lupron®, which cost was based upon, in whole or in part, the published AWP for Lupron®. Excluded from the Class are Defendants, any entity in which Defendants have a controlling interest, and their legal representatives, heirs, successors, and any governmental entities.

NUMEROSITY

42. The proposed Class is so numerous that joinder of all of its members is impractical. Thousands of patients each year are prescribed and pay for Lupron®.

COMMON QUESTIONS OF LAW AND FACT

43. Virtually all of the issues of law and fact in this class action are common to the Class and include at least the following:

a. Whether the Defendants engaged in the unlawful conduct and conspiracy as alleged herein;

b. Whether the Defendants unlawfully set the AWP for Lupron®;

c. Whether Defendants unlawfully marketed and promoted the spread between the AWP and the actual cost for Lupron® to medical providers;

d. Whether Defendants provided free samples of Lupron® and other financial inducements to medical providers;

e. Whether Defendants encouraged medical providers to charge patients for free samples provided by sales representatives, or were otherwise aware that medical providers in fact charged patients for such free samples;

f. Whether the Defendants engaged in a pattern and practice of deceiving and defrauding the Class and suppressing their unlawful conduct and conspiracy;

g. Whether the Defendants violated state consumer protection statutes;

h. Whether the Defendants violated state antitrust statutes;

i. Whether Plaintiffs and the members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;

j. Whether Plaintiffs and members of the Class are entitled to an award of reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

TYPICALITY

44. Plaintiffs' claims are typical of the claims of other members of Class. Plaintiffs and all members of the Class sustained damages. The financial losses of each member of the Class were directly caused by the Defendants' unlawful conduct and conspiracy.

ADEQUACY OF REPRESENTATION

45. Plaintiffs can and will fairly and adequately represent and protect the interests of the Class and Plaintiffs have no interests that conflict with or are antagonistic to the interests of Class members. Plaintiffs have retained attorneys competent and experienced in class actions, including consumer fraud and protection class actions. No conflict exists between Plaintiffs and the Class members.

SUPERIORITY

46. A class action is superior to any other available method for the fair and efficient adjudication of this controversy and common questions of law and fact overwhelmingly predominate over any individual questions that may arise.

47. The prosecution of separate actions by individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class which would establish incompatible standards of conduct for the Defendants or adjudication with respect to individual members of the Class which would as a practical matter be dispositive of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

FACTUAL ALLEGATIONS

48. There are hundreds of thousands of men in the United States who have prostate cancer. The hormone, testosterone, naturally produced by men, promotes the growth and spread of prostate cancer. One method of treatment of prostate cancer has been the suppression or elimination of testosterone in men suffering from that disease. Testosterone in a man suffering from prostate cancer can be eliminated through the surgical removal of the testicles by a procedure called an orchiectomy. Alternatively, a man's production of testosterone can be suppressed through the administration of either a drug that acts to suppress testosterone production, such as Lupron® or Zoladex (a direct competitor of Lupron®).

49. In the 1980s, Defendants Abbott, Takeda and TAP began marketing Lupron® as a treatment for prostate cancer. In marketing Lupron®, these Defendants employed and maintained extensive marketing and sales departments. Since at least the early 1990's, these Defendants primarily sold and provided Lupron® to medical providers across the country.

50. Lupron® and Lupron Depot® are used principally for the palliative treatment of advanced prostate cancer in men, the treatment of endometriosis and infertility in women, the

treatment of central precocious puberty in children and for the preoperative treatment of patients with anemia caused by uterine fibroids.

51. Lupron® is administered to patients in liquid form by intramuscular injection, typically in the buttocks or arm, by a physician or a nurse under the supervision of a physician. At various times in the 1990s, and continuing to the present, Lupron® was available in daily, one month, three month and four month doses. It is typical that a patient whose prostate cancer is being treated with Lupron® would receive regular injections of Lupron® for the remainder of his life.

52. Lupron® is also widely prescribed for women in the treatment of endometriosis and as part of infertility treatment.

53. Lupron® is prescribed for children suffering from central precocious puberty.

THE MEDICARE INSURANCE PROGRAM

54. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

55. The U.S. Department of Health and Human Services ("HHS") is an agency of the United States and is responsible for the funding, administration and supervision of the Medicare Program. The Health Care Financing Administration ("HCFA") is a division of HHS and is directly responsible for the administration of the Medicare Program. HCFA, in discharging those responsibilities, contracted with private insurance companies, known as intermediaries and carriers, to receive, review, and pay appropriate claims for reimbursement for the provision of care to Medicare beneficiaries.

56. The Medicare Program, as a general matter, does not cover the cost of prescription pharmaceuticals which a Medicare beneficiary obtains pursuant to a prescription and thereafter self

administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered by a medical provider. Since Lupron® is an injectable drug, it is covered under Medicare Part B.

57. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug based upon the payment methodology set forth in 42 C.F.R. §405.517, which regulation was published in the Federal Register on November 25, 1991 and became effective on or about January 1, 1992.

58. Prior to January 1, 1998, the Medicare Part B allowed amount for injections of Lupron® was on the basis of the lower of the "estimated acquisition cost" ("EAC") or the national "average wholesale price" ("AWP") for the drug. The EAC for a drug is determined based on surveys of the actual invoice prices paid for the drug, taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." The AWP is reported in *The Red Book* and other pricing publications and databases used by the pharmaceutical industry. Historically, it has been the AWP that has been used to develop Medicare reimbursement for prescription drugs. On January 1, 1998, Medicare Part B was changed to provide that the allowed amount would be based upon the lower of the actual charge on the Medicare claim for benefits or 95 percent of the AWP for the drug.

59. Medicare Part B reimburses medical providers (or Medicare "carriers") 80% of the allowable amount for prescription drugs. The remaining 20% is paid by the Medicare beneficiary, and is called the "co-payment" amount. All Medicare carriers are required by law to not only send the patient a bill for the 20% co-payment, they are also required to make attempts beyond merely billing to collect that amount. In addition, Medicare beneficiaries under Part B are required to pay

an annual deductible amount before Part B benefits are payable. Accordingly, all Medicare beneficiary members of the Class may have paid some or all of the inflated co-payment amount.

60. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Medicare has stated that outpatient drugs and biologicals are paid based on the lower of the actual billed charge or 95 percent of the AWP reflected in pharmaceutical industry publication sources such as the *Red Book*, *Blue Book*, or *Medispan*.

61. The *Red Book* and other publications published AWP's for the various dose forms of Lupron®, as well as the competitor drug Zoladex and many other drugs. In periodically announcing the AWP for Lupron®, the *Red Book* and other publications simply published the prices that were supplied to them by Defendants. Defendants knew that they could and did directly control and raise the AWP for Lupron® at any time by simply forwarding to the *Red Book*, or any other publication, a new and higher AWP.

62. On May 23, 1999, *The Chicago Tribune* reported that a spokesman for the publisher of the *Red Book*, Medical Economics Co., stated that the AWP for Lupron® that appears in the *Red Book* is supplied by TAP. In fact, in a June 1996 Dow Jones News Article, it was reported that Phil Southerd, an associate product manager of the *Red Book*, stated that the *Red Book* merely publishes prices that are faxed right from the manufacturer.

63. There are significant discrepancies between the AWP set by Defendants for Lupron® in the *Red Book* for reimbursement under Medicare and the prices charged for Lupron® by Defendants to private sector purchasers. The AWP for Lupron® set by Defendants is neither an "average" nor "wholesale."

64. Therefore, Defendants' conspiracy in violation of the PDMA to artificially inflate the AWP for Lupron® above the actual average wholesale price directly caused Plaintiff and members of the Class, who paid all or part of the 20% Medicare co-payment for Lupron®, to substantially overpay.

OTHER GOVERNMENT AND PRIVATE ASSISTANCE PROGRAMS

65. In addition to Medicare, other government assistance programs provide for partial reimbursement of certain prescription drugs, including Lupron®, and utilize the AWP as the basis for reimbursement. These programs include TRICARE (formerly CHAMPUS), the medical assistance program for both active and retired members of the U.S. armed forces, and Medicaid, the state administered medical benefits program.

66. Moreover, there are government assistance programs that provide medical assistance to patients through certain private health insurance carriers. These programs also provide limited coverage for partial reimbursement of prescription drugs, including Lupron®, and utilize the AWP for reimbursement.

67. CHAMPUS, the prior name for TRICARE, provides for partial reimbursement of Lupron® depending on the patient's active duty status and the program in which he or she is enrolled. At the time he took Lupron®, Mr. Nelson was enrolled in a retirement benefits program of CHAMPUS which reimbursed only 75 percent of the cost of the drug. The remaining 25 percent had to be paid out-of-pocket by Mr. Nelson.

68. Therefore, Defendants' conspiracy in violation of the PDMA to artificially inflate the AWP for Lupron® above the actual wholesale price directly caused Plaintiff Nelson and other Government and Private Assistance Patient members of the Class, who paid all or part of the

percentage co-pay for Lupron® under government and private assistance programs, to substantially overpay.

PATIENTS WITHOUT INSURANCE COVERAGE

69. There are patients throughout North Carolina and the country who had no medical assistance coverage for the cost of their Lupron® prescriptions, which costs were based upon the published AWP. These No Assistance Patients paid the full measure of the percentage overcharge in the cost of Lupron® caused by Defendants' conspiracy.

DEFENDANTS' FRAUDULENT CONDUCT AND CONSPIRACY

ARTIFICIALLY INFLATING THE AVERAGE WHOLESALE PRICE

70. During the Class Period, Defendants deliberately and intentionally charged medical providers across the United States a price substantially less than the AWP that Defendants had reported to *Red Book* and other publications for government and private assistance reimbursement. Defendants perpetuated this scheme so that the medical providers who purchased Lupron® at a low cost could bill government assistance programs, private insurance companies and/or individual patients at the inflated AWP and earn a substantial profit from the "spread" between the retail cost and reimbursement rate or amount charged to patients. This profit potential was created and marketed by Defendants to influence medical providers' decisions to recommend Lupron® and thereby increase Defendants' market share and revenues, and obtain other benefits.

71. Defendants knew and understood that government assistance programs and private insurers relied upon the *Red Book* and other publications to establish the AWP, and because Defendants controlled the published AWP, Defendants could manipulate the medical providers' profit. By artificially inflating the amount of profit obtained by physicians from government and

private assistance programs, and from the members of the plaintiff Class, Defendants directly increased the demand for Lupron® and, accordingly, Defendants could inflate the amount of market share and profit they received from Lupron®.

72. As part of Defendants' scheme to increase their market share and revenues, they also increased Lupron® sales by telling medical providers to charge government and private assistance programs, and individual patients, the AWP then published in the *Red Book* and related publications. According to Criminal Informations filed against several doctors and internal company documents, Defendants referred to this inflated profit, and the corresponding inducement to the physicians, as their "Return to Practice" program, among other names. Defendants referred to the profit that the doctor could obtain by prescribing Lupron® and billing the assistance programs and patients at the published AWP as money going to the doctor from "[Defendants'] Checkbook." Defendants knew and understood that, because the government and private assistance programs relied upon the *Red Book* and like publications to establish AWP's, and because Defendants could precisely control the AWP as published in these publications, Defendants could increase the AWP whenever they so desired to create the profit obtained by physicians from the assistance programs and the plaintiff Class. Accordingly, Defendants could control the amount of the financial incentive, or "Return to Practice," that a physician would receive by prescribing Lupron® to their patients and billing assistance programs and patients at the AWP established by Defendants. *See, e.g.*, Information of *United States of America v. Spinella* (D. Mass. Dec. 8, 2000).

73. For example, the Criminal Information against Dr. Spinella states that, on or about August 24, 1995, in an attempt to get Dr. Spinella to reverse his decision to prescribe Zoladex, rather than Lupron®, an employee of Defendants left at his office a document created by Defendants

demonstrating to the doctor the amount of profit that he could earn through Defendants' "Return to Practice" program from the use of Lupron®. Specifically, the document showed that Dr. Spinella could earn as much as $7,000 per year more by using Lupron® instead of Zoladex. *See* Information of *United States of America v. Spinella* (D. Mass. Dec. 8, 2000).

74. The increase of $7,000 per year was based on the "spread" between Dr. Spinella's actual costs and the artificially inflated AWP set by Defendants used by government and private assistance programs for reimbursement.

75. Defendants' marketing and sales documents, which were prepared and disseminated to their employees and agents, compared the cost of Lupron® to that of its competitor drug Zoladex. For example, in 1996, Defendants prepared marketing materials for medical providers showing how they could make money by purchasing Lupron® from Defendants. As Defendants' marketing and sales materials indicated, in 1996, the AWP for Lupron® as reported for Medicare reimbursement was $515.63. However, in 1996, the actual price paid by the medical provider to Defendants for Lupron® ranged from a high of only $412.50 to a low of $350.81, if volume discounts were achieved. *See* Information of *United States of America v. Spinella* (D. Mass. Dec. 8, 2000).

76. Other documents created and disseminated by Defendants compared the AWP's and the actual "costs" for Lupron® and Zoladex so that medical providers could easily see the different "Return-to-Practice" amounts are available for different levels of purchases.

77. Defendants used the artificially inflated AWP as a means of marketing Lupron®. Specifically, when employees of Defendants talked to providers about their choice of using Lupron®, rather than Defendants' competitor medication Zoladex, Defendants emphasized that, because the AWP for Lupron® was high, the monetary return to the providers was better if they used Lupron®.

Internal documents from Defendants specifically show that they used the spread to create greater demand for Lupron®. One such internal document stated:

> As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would stop if the allowable issue was taken care of.

The benefit of Defendants' illegal marketing and sales scheme is shown in increased market share and sales of Lupron®. In 2000, Lupron® sales were nearly $800 million as compared to $584 million in 1998. Most of the revenue obtained from Lupron® was from reimbursement from government and private assistance programs and the plaintiff Class.

USE OF FREE SAMPLES

78. Defendants, through their employees and agents, also provided free samples of Lupron® to medical providers. In some years, sale representatives of TAP were provided with free samples for distribution to medical providers worth approximately $40,000. These free samples were used to off-set the total cost associated with Lupron® purchases, thereby increasing the spread. Moreover, Defendants specifically told medical providers that they could and should bill government and private assistance programs for the free samples. Defendants were aware that medical providers were billing government and private assistance programs for the free samples.

79. One of Defendants' sales representatives called on Dr. Joseph Spinella in 1995 and reported to a District Manager employed by Defendants in Massachusetts. That District Manager supervised a number of Defendants' sales representatives who called upon urologists in Connecticut, Massachusetts, Maine and Rhode Island. From time to time, beginning in or about 1995, that Massachusetts District Manager informed Defendants' sales representatives that free doses of

Lupron® could be offered to physicians to induce them to prescribe Lupron® to their patients and to keep them from switching patients to Zoladex. Defendants' sales representatives, supervised by that same District Manager, sent to the District Manager so-called Weekly Activity Reports and sales call notes, or portions thereof, which contained requests by physicians for samples, and the offer and delivery of samples to physicians to keep and to maintain their Lupron® business. *See* Information of *United States of America v. Spinella* (D. Mass. Dec. 8, 2000).

80. The medical providers were a necessary component of Defendants' scheme, but they did not control the setting of the AWP or other aspects of the scheme. For example, in April 2001, Dr. Joel Olstein, a Lewiston, Maine urologist, was charged with conspiring with TAP to bill insurance companies for free samples of Lupron®. In a telephone interview with Dr. Olstein, conducted by Chicago Tribune reporter Bruce Japsen on April 11, 2001, Dr. Olstein said that he planned to plead guilty in exchange for his cooperation in the investigation. He explained, "my plea is a conspiracy with TAP.... Did they tell me what to do? On some level there was some understanding.... For every new patient I started on Lupron®, they provided me a free dose of the drug." He added,"they wanted me to carefully track how many new patients I started on Lupron® and we kept lists. Anybody in practice knows how to bill for free samples."

81. The Criminal Information against Dr. Olstein specifically alleges "the core objective of this conspiracy for all participants was to obtain money from the patient's health care insurers through the prescription of Lupron®. It was the objective of [TAP] in this conspiracy to provide free doses or samples of Lupron Depot®, as well as other things of value, including money, to physicians as an inducement to those physicians to order Lupron Depot®."

OTHER FINANCIAL INDUCEMENTS

82. Defendants have also provided and/or arranged for many other financial inducements to stimulate sales of Lupron® at the expense of Plaintiffs and the Class. Such inducements included, but were not limited to, kickbacks which consisted of free drugs, trips to resorts, free consulting services to doctors and other customers, and debt forgiveness, among other things.

83. Defendants conspired and agreed to accomplish the fraudulent scheme set forth herein in order to increase the sale of Lupron®, and committed acts in furtherance of this conspiracy which are outlined in this Complaint.

84. In furtherance of this scheme to defraud government and private assistance programs and the Plaintiff Class, Defendants have created a centralized national marketing and sales plan which was implemented through their employees and agents in the following manner, among others:

a. Setting actual wholesale prices at which Lupron® was sold;

b. Setting the AWP in the *Red Book* and other similar publications which was materially greater than the average actual wholesale price;

c. Contacting the *Red Book* and other industry publications for the purpose of setting and controlling the listed AWP;

d. Sending informing to or otherwise contacting medical providers about both the *Red Book* quoted AWP and the average actual wholesale price for Lupron®;

e. Creating and disseminating marketing and sales materials that showed the spread between the average actual wholesale price and the reported AWP;

f. Creating and disseminating marketing and sales materials for medical providers discussing how the use of free samples can increase their profits;

g. Creating and disseminating marketing and sales materials for medical providers discussing other financial inducements available from Defendants for the use of Lupron®;

h. Inducing Government and Private Assistance Patients to pay inflated co-payments for Lupron® based upon the inflated AWP;

i. Inducing No Assistance Patients to pay inflated prices for Lupron® based upon the inflated AWP;

j. Receiving the proceeds and benefits of their fraudulent scheme; and

k. Distributing the proceeds and benefits of their fraudulent scheme to medical providers in the form of free samples, lower average actual wholesale price's for Lupron® and other financial inducements.

85. Defendants concealed their fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWP was set and the actual reported AWP's. Defendants also prevented Class Members from knowing what the actual costs for Lupron® were, and they failed to inform Class Members of the usage of free samples and of their providing other financial incentives to medical providers to induce them to use Lupron®. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

86. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice or learn of the factual basis for their claims in this Complaint or their injuries suffered therefrom until recently.

DEFENDANTS' INDICTMENTS AND GUILTY PLEAS AND WHISTLEBLOWER ACTIONS AGAINST THEM

INDICTMENTS AND GUILTY PLEA OF ABBOTT, TAKEDA AND TAP

87. In late September, 2001, Defendants Abbott, Takeda and TAP agreed to plead guilty to a Criminal Information charging them with a conspiracy to violate Title 21 United States Code Sections 333(b) and 331(f) in violation of Title 18 United States Code Section 371 ("Conspiracy to commit offense or to defraud United States"), settling charges by the U.S. Attorney's Office that they manipulated the price used for government and private reimbursement to ensure medical providers would make a profit in their prescriptions of Lupron®. *See* Letter Agreement dated September 28, 2001 between the United States Department of Justice, the United States Attorney for the District of Massachusetts and TAP attached hereto as Exhibit "A" (hereinafter "TAP Plea Agreement").

88. Specifically, these Defendants agreed to plead guilty to a conspiracy in violation of the PDMA and to pay a fine of $875 million. These Defendants agreed to plead guilty to fraudulently pricing and marketing Lupron® during the period 1991 through 1998.

89. The fines paid consisted of a $290 million criminal fine, $559.5 million in civil liabilities for filing false and fraudulent claims, and $25.5 million in civil liabilities to be paid to the fifty (50) states and the District of Columbia, plus interest in the amount of approximately $9 million.

90. In exchange for their agreement to settle the government's claims, the government agreed not to further prosecute TAP or to exclude TAP from participating in Medicare and other government assistance programs.

91. In addition to fraudulently pricing and marketing Lupron®, the conspiracy among Defendants involved various employees of TAP being involved in an illegal kickback scheme involving Lupron®. Among other things, the criminal conspiracy involved providing doctors with thousands of free samples of Lupron® for which doctors were encouraged to and did in fact bill government assistance programs and their patients. These free samples were worth hundreds of dollars each and were used as incentives to get medical providers to prescribe Lupron® over competing drugs, such as Zoladex, which were less expensive. Accordingly, these Defendants chose not to compete on price, but instead chose to compete by providing illegal kickbacks and incentives.

92. In addition to the fines, and as a further condition of the settlement, Defendants Abbott, Takeda and TAP agreed to report the true price of Lupron® to the government and to allow regular auditing of their sales and marketing practices.

INDICTMENTS OF TAP EMPLOYEES

93. In addition to the guilty pleas by these Defendants, a Boston grand jury indicted six (6) current and former employees of TAP for illegal conduct. Two (2) of these employees are still working at TAP, while the four (4) others have left the company, including two (2) from Massachusetts, Janice Swirski of Chestnut Hill, a former National Account Manager, and Kimberlee Chase of Dover, a former District Manager.

94. The Boston indictments allege that the sales people and managers called on doctors in Massachusetts and other states and offered them bribes, including trips to resorts, debt forgiveness, televisions and VCRs, and cash in the form of "educational grants," as well as free drug samples.

WHISTLEBLOWER ACTIONS

95. According to the indictments, Swirski, a local TAP employee, was involved in the offer of an illegal bribe to the Tufts Health Plan of Waltham, Massachusetts, one of two whistle blowers involved in the criminal prosecution of these Defendants. The indictments charge that Swirski first offered the Tufts Medical Director of Pharmacy Programs, doctor Joseph Gerstein, $40,000 in grants that he could use for any purpose if he would reverse a decision to make Zoladex the preferred Tufts drug.

96. The general counsel for Tufts, James Roosevelt, Jr., said Gerstein was outraged by the offer and, with the support of Tufts, went directly to prosecutors and blew the whistle on TAP.

97. Swirski and Chase then increased their offer to $65,000, according to the indictments, an offer that Gerstein and prosecutors allegedly caught on tape.

98. In exchange for his cooperation with prosecutors, Gerstein, along with Tufts, will share a reward of $17.2 million. Tufts officials said they would donate their portion to charity.

99. In addition to the Tufts whistleblower situation, the fraudulent scheme and conspiracy came to light after a former TAP Vice President of Sales, Douglas Durand, quit his job in 1996, filed a lawsuit and blew the whistle on the company's operations. According to his attorney, Mr. Durand quit his job after being asked to participate in marketing ventures he considered unethical. He provided prosecutors with detailed accounts of how the company allegedly manipulated the average price used for government reimbursement. In exchange for his cooperation, Mr. Durand is expected to receive $77.9 million as part of the settlement under the Whistle Blower's Statute.

INDICTMENTS AND GUILTY PLEAS OF DEFENDANTS JETT, COLEMAN, HIDALGO AND HACK

100. Around the same time that the TAP employees were being indicted in Boston, three employees of a subsidiary company of J&J were indicted in the same conspiracy to defraud the government, along with the owner and operator of a national oncology company. In April 2001, Criminal Informations were filed in the United States District Court for the District of Connecticut against David Jett, Christopher Coleman and Scott Hidalgo, all sales representatives and employees of Defendant Indigo, the wholly owned subsidiary of Defendants Ethicon and J&J. In addition, a Criminal Information was filed in this same Court against Eddy J. Hack, the owner and operator of Oncology Solutions a/k/a International Oncology Network.

101. These Criminal Informations all charged Jett, Coleman, Hidalgo and Hack with participating and aiding and abetting in the same conspiracy to defraud the government charged against Defendants Abbott, Takeda and TAP, and to which they pled guilty, in violation of the federal conspiracy statute, 18 U.S.C. § 371. These four defendants all pled guilty to the charged conspiracy and they each were sentenced to probation and paid fines ranging from $100 to $26,870.04.

DEFENDANTS' UNLAWFUL CONDUCT IN NORTH CAROLINA AND THROUGHOUT THE COUNTRY

102. By virtue of Defendants' agreement to plead guilty to a conspiracy to violate the PDMA, and to pay fines to resolve both criminal and civil charges against them, it is clear that their conduct had a nationwide effect both upon residents and consumers in North Carolina and throughout the country.

103. Defendants' guilty plea and settlement included the sum of $25.5 million to be paid to the 50 states and the District of Columbia to resolve civil liabilities. Accordingly, Defendants have agreed that their unlawful conduct and conspiracy has effected residents and consumers throughout the 50 states and the District of Columbia, including North Carolina.

104. In addition, one of the six (6) TAP employees who was indicted by the grand jury in Boston, Janice Swirski, was a former National Account Manager whose job presumably involved the administration of accounts throughout the country. Accordingly, her indictment, as well as the indictments of other TAP employees and sales personnel, on grounds that she and others offered bribes to doctors and medical care providers to switch from Zoladex to Lupron®, further evidences that Defendants' conduct had a nationwide impact and effect.

105. Defendants Jett, Coleman, and Hidalgo, sales representatives for Indigo in both North Carolina and Florida, through their guilty pleas, also admitted the multi-state scope and impact of this conspiracy. Similarly, the plea of Defendant Hack, owner and operator of a national oncologic network, evidences the nationwide scope of the conspiracy.

106. In addition, a number of urologists have been indicted by prosecutors charging them with defrauding Medicare by charging more for prescriptions of Lupron® than they were charged by the manufacturer. Urologists in the states of Florida, Massachusetts, Indiana, Connecticut, and Maine have all been so charged. In addition, several other urologists and doctors have told newspapers that TAP representatives contacted them and explained to them how much money they could make by charging the AWP for Lupron®. These doctors and medical care providers practice in states such as South Carolina, Kentucky, Illinois, and Wisconsin, among others.

107. In January, 2001, the United States Attorney's Office in Connecticut filed charges against two (2) Florida doctors who ordered excess supplies of Lupron® and then resold them at higher prices in other states, according to court papers. The two urologists agreed to forfeit $1.1 million to the federal government.

108. In addition to these known, isolated occurrences, it is known that federal investigators are looking into the marketing of Lupron® and have asked to see the financial records of over 100 urologists throughout the country, according to the general counsel for the American Urological Association.

109. Finally, it is believed and therefore averred that sales presentations made by TAP employees included a company-supplied program that listed how much doctors could collect if they billed Medicare for free samples. It is further believed, and therefore averred, that such presentations were given to doctors and medical care providers throughout the country by sales employees of TAP and/or Abbott also located throughout the country.

TOLLING OF THE STATUTE OF LIMITATIONS

110. Plaintiffs had no knowledge of the conspiracy, concerted action and other unlawful conduct alleged herein, or of any facts that might have led to the discovery thereof in the exercise of reasonable diligence, until early October, 2001 when it was announced that Defendants Abbott, Takeda and TAP agreed to plead guilty to a conspiracy to violate the PDMA. Plaintiffs could not have discovered the conspiracy, concerted action or other unlawful conduct alleged herein at an earlier date by the exercise of due diligence because of the deceptive practices and techniques of secrecy employed by Defendants and their co-conspirators to avoid detection of and to conceal their unlawful conduct

and conspiracy. These techniques of secrecy included, but were not limited to, secret meetings and communications, misstatements about the AWP, and other conduct alleged herein.

111. Because the unlawful conduct and conspiracy was kept secret by Defendants and their co-conspirators, Plaintiffs were unaware of the fact that the prices of Lupron® were secretly agreed upon and artificially set as alleged herein.

112. By reason of the foregoing, the claims of Plaintiffs and members of the Class are timely under any applicable statute of limitations (as tolled by the filing of this class action Complaint) pursuant to the discovery rule and the doctrine of fraudulent concealment.

113. The Defendants have been aware of their unlawful conduct and conspiracy since at least 1991, and probably from before then.

114. Despite this knowledge and awareness, the Defendants have continued to promote and sell Lupron® at artificially inflated prices.

115. The Defendants' failure to properly disclose their unlawful conduct and conspiracy, and other acts and omissions as alleged herein, was and is willful, wanton, malicious, outrageous, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of the Plaintiffs and members of the Plaintiff Class.

COUNT I

UNJUST ENRICHMENT

116. Plaintiffs hereby incorporate by reference thereto the averments of paragraphs 1 through 115 hereof as if fully set forth here and further allege as follows.

117. By engaging in the conduct described in this Complaint, Defendants have knowingly obtained benefits from Plaintiffs and the Class under circumstances such that it would be inequitable and unjust for these Defendants to retain them.

118. Defendants have collected payments for Lupron® from Plaintiffs and the members of the Class that vastly exceeded the payments to which Defendants were entitled as a matter of law. Moreover, Defendants have admitted that they unlawfully inflated the price of Lupron® paid by Plaintiffs and the Class and supplied medical providers with free samples of Lupron® and encouraged them to charge patients for such samples, in violation of the PDMA and other federal and state laws.

119. Thus, Defendants will be unjustly enriched if they are permitted to retain the full amounts paid to them by Plaintiffs and the members of the Class.

120. Plaintiffs and the members of the Class are therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the profits derived by Defendants by means of the overcharges they imposed upon Plaintiffs and the members of the Class.

121. Plaintiffs and the members of the Class have no remedy at law to prevent Defendants from continuing the inequitable conduct alleged herein.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

COUNT II

FRAUD

122. Plaintiffs and the Class hereby incorporate by reference thereto the averments of paragraphs 1 through 121 hereof as if fully set forth here and further allege as follows.

123. By engaging in the acts and omissions alleged in this Complaint, Defendants have committed fraud on the Plaintiffs and the Class.

124. These Defendants intended that Plaintiffs and the Class would rely on their statements and representations with respect to the inflated AWP, among other things, to the detriment of Plaintiffs and the Class. Plaintiffs and the Class did in fact reasonably rely on the false representations and statements of these Defendants and suffered injury and damages thereby, as more fully set forth herein.

125. In addition, these Defendants concealed and suppressed material facts about their unlawful agreements and discussions with one another and others, and they concealed and suppressed their unlawful acts and omissions as set forth more fully herein. Among other things, these Defendants concealed and suppressed the fact that the AWP's upon which the prices paid for Lupron® by Plaintiffs and the Class were based were artificially inflated, thereby causing Plaintiffs and the Class to pay more for Lupron® than they otherwise would have.

126. Plaintiffs and the Class were unaware of the above-referenced facts, and would not have paid the artificially inflated prices for Lupron® that they did had they known of the facts Defendants concealed and suppressed.

127. Indeed, as soon as these facts came to light as a result of the government's investigation, Defendants, as part of their settlement of the criminal action, agreed to report the true,

lower prices of Lupron® to the government and to allow regular auditing of their sales and marketing practices. As a result of this settlement, the prices paid for Lupron® by Plaintiffs and the Class should be lower.

128. As a direct and proximate result of Defendants' fraudulent conduct, and the concealment and suppression of material facts by Defendants, Plaintiffs and the Class have suffered and will continue to suffer damages.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

COUNT III

CIVIL CONSPIRACY

129. Plaintiffs and the Class hereby incorporate by reference thereto the averments of paragraphs 1 through 128 hereof as if fully set forth here and further allege as follows.

130. Beginning at least as early as 1991, the exact date being unknown to Plaintiffs and the Class, and continuing thereafter until at least October, 2001, Defendants and their co-conspirators engaged in a continuing conspiracy to violate the PDMA and to defraud the Plaintiffs and the Class by causing Plaintiffs and the Class to pay more for Lupron® than they otherwise would have in the absence of Defendants' conspiracy.

131. According to the United States Department of Justice, on or before October 3, 2001, Defendants Abbott and Takeda, by and through their joint venture, TAP, agreed to plead guilty to a federal conspiracy to violate the PDMA in violation of 18 U.S.C. § 371, and to pay a $290 million criminal fine, the largest criminal fine ever in a U.S. health-care fraud prosecution case. Additionally, these Defendants agreed to settle the government's claims for $875 million, plus

interest, which consisted of the $290 million criminal fine, $559.5 million in civil liabilities for filing false and fraudulent claims, and $25.5 million in civil liabilities to fifty states and the District of Columbia.

132. Six individual employees of TAP were also indicted for their participation in the federal conspiracy, along with eight urologists/urologic practices through the country.

133. Moreover, three employees of J&J's subsidiary, Indigo, and the owner of the largest community-based oncologist network, all pleaded guilty to the same federal conspiracy.

134. Pursuant to their widespread conspiracy alleged herein and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to defraud the Plaintiffs and the Class. Those activities include the following:

(a) Defendants discussed and agreed among themselves and with their co-conspirators that they would fix the AWP for Lupron®;

(b) Defendants discussed and agreed among themselves and with their co-conspirators that they would provide free samples to medical providers; and encourage medical providers to charge for such samples;

(c) Defendants discussed and agreed among themselves and with their co-conspirators that they would provide other financial inducements and incentives to medical providers to prescribe Lupron® instead of competitor drugs, such as Zoladex; and

(d) Defendants discussed and agreed among themselves that they would market and promote the spread between the AWP and the actual wholesale cost for

Lupron® as an incentive for medical providers to prescribe Lupron® instead of competitor drugs, such as Zoladex.

135. Defendants performed these acts alleged herein in furtherance of the common plan or design for the conspiracy with knowledge of the injury and damage it would cause to Plaintiffs and the Class and with intent to cause such injuries or with reckless disregard for the consequences.

136. As a direct and proximate result of Defendants' conspiracy as alleged herein, Plaintiffs and the Class have been injured and damaged, and Defendants are jointly and severally liable for such injuries and damages.

WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully seek the relief set forth below.

COUNT IV

CONCERT OF ACTION

137. Plaintiffs and the Class hereby incorporate by reference thereto the averments of paragraphs 1 through 136 hereof as if fully set forth here and further allege as follows.

138. Beginning at least as early as 1991, the exact date being unknown to Plaintiffs and the Class, and continuing thereafter until October, 2001, Defendants and their co-conspirators engaged in concerted activity and/or a concert of action with each other to commit fraud and other tortuous acts and omissions on the Plaintiffs and the Class, causing Plaintiffs and the Class to pay more for Lupron® than they otherwise would have in the absence of Defendants' concerted activity.

139. Defendants acted in concert with one another, and with medical providers throughout the country, to commit fraud on Plaintiffs and the Class. Moreover, Defendants acted pursuant to a common design or plan with respect to the commission of such fraud.